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K011976

JUL 16 2001

Exactech® Optetrak ™ Total Knee System
Size 0 / 1 Delta Line Extension

510(k) Summary of Safety and Effectiveness
Special 510(k)

Sponsor: **Exactech® Inc.**
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FDA Establishment Number 1038671

Contact: **Gary J. Miller, Ph.D.**
V.P. of Research and Development

Date: **June 13, 2001**

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Classifications / Proprietary Names:

Classification Name:	Prosthesis, knee, patellofemorotibial, semi-contrained, cemented, polymer/metal polymer
Trade / Proprietary Model Names:	Optetrak Total Knee System Size 0 / 1 Delta
Product Code:	JWH
C.F.R. Section:	888.3560
Device Class:	II
Classification Panel:	Orthopedic

Legally Marketed Devices for Substantial Equivalence Comparison:

Exactech Predicate Devices

Model	Manufacturer	510(k) Number
Optetrak CR Femoral	Exactech	#K932690
Optetrak PS Femoral	Exactech	#K933494
Optetrak Porous CR Femoral	Exactech	#K935726
Optetrak PS Tibial Insert	Exactech	#K933610
Optetrak CR Tibial Insert	Exactech	#K932776
Optetrak CC Tibial Insert	Exactech	#K954208
Optetrak Finned Tibial Tray	Exactech	#K932776
Optetrak Finned Porous Tibial Tray	Exactech	#K936079
Optetrak Trapezoidal Tibial Tray	Exactech	#K933610
Optetrak Tibial Augments	Exactech	#K933610

Predicate Devices from other Manufacturers

Nexgen	Zimmer	----------
Maxim	Biomet	----------
PFC	Johnson & Johnson	----------

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Device Information:

INDICATIONS

The OPTETRAK® Total Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

CAUTION: For cemented use only in the USA.

CONTRAINDICATIONS

The OPTETRAK® Total Knee Systems are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, patients without sufficient soft tissue integrity to provide adequate stability, and in patients with either mental or neuromuscular disorders that do not allow control of the knee joint, and in patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

DEVICE DESCRIPTION

Femoral Components

The proposed Optetrak Line Extension (Size 0) femoral components are composed of Cobalt Chromium alloy (ASTM F-75). The proposed Size 0 femoral component is available in the cruciate retaining (CR) and posterior stabilized (PS) styles. The design incorporates the same design features as the predicate Optetrak femoral components on a smaller scale. The existing Optetrak patellar components (#K932690) are fully compatible with the proposed Optetrak Line Extension (Size 0) femoral components.

Tibial Components

The proposed Line Extension (Size 0 and 1 Delta) tibial inserts are composed of Ultra High Molecular Weight Polyethylene – UHMWPE (ASTM F648). The proposed insert components for the Size 0 are available in the cruciate retaining (CR) and posterior stabilized (PS) styles, similar to those in the existing Optetrak system. The proposed insert components for the Size 1 Delta are available in cruciate retaining (CR), posterior stabilized (PS), and constrained condylar (CC) styles, similar to those in the existing Optetrak system. The predicate and proposed models have the same locking mechanism for assembly of the polymer insert into the tibial tray.

In addition, the CC spine stiffener screw line has been expanded to accommodate the Size 1 Delta CC tibial inserts. This screw acts as a stabilizing force in the spine of the CC tibial insert. The screw varies in length according to tibial insert thickness and is packaged with the appropriate insert.

Tibial Tray Components
Optetrak Line Extension (Size 0 and 1 Delta) tibial tray components are designed to accept the modular tibial insert (described above). The proposed tibial tray components are composed of Titanium alloy (Ti 6Al 4 V), which is the same as the predicate Optetrak trays. The locking mechanism is identical to that of the predicate Optetrak system. Similarly, the proposed line extension offers a finned stem tray version and a trapezoid stem tray version. Both designs have tibial component options that allow for upsizing and downsizing on the tibia.

Augmentation Components
The proposed Optetrak Line Extension (Size 0 and 1 Delta) tibial augment components are designed to work with their corresponding Size 0 and 1 Delta trapezoid tibial trays. The components are composed of Titanium alloy (Ti 6 Al 4V) conforming to ASTM F136.

PACKAGING MATERIALS

Material	Composition
Inner / Outer Trays	PETG – 0.040" thickness
Tray Lids	Spun-Bonded Olefin - Tyvek®
Inserts	Medium grade LD45 Foam
Box	Heavy weight cardboard
Outer Shrink-Wrap	Clear, Light-Weight Plastic
Shipping Cartons	Heavy-weight Corrugated Cardboard

STERILIZATION INFORMATION

Method: Gamma radiation (Cobalt 60 source)
Dose: 25 – 37 kGy
Sterility Assurance Level (SAL): 10^{-6}

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PERFORMANCE DATA

Design assurance reviews were conducted to verify that the implant performance would be adequate for anticipated *in vivo* loading. These activities did not indicate the need for additional testing beyond that performed for validation of the previously mentioned predicate Optetrak models.

We conclude that the Optetrak Size 0 / 1 Delta components are substantially equivalent to other devices legally marketed in the United States, most notably Exactech's predicate Optetrak products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 6 2001

Gary J. Miller, Ph.D.
Vice President of Research
and Development
Regulatory Representative
Exactech, Inc
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K011976
Trade Name: Optetrak Total Knee System
Size 0/1 Delta
Regulation Number: 888.3560
Regulatory Class: II
Product Code: JWH
Dated: June 21, 2001
Received: June 25, 2001

Dear Dr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak Total Knee System
Size 0 / 1 Delta

Indications for Use

510(k) Number: K011976

Device Name: Optetrak Total Knee System
Size 0 / 1 Delta

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for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011976

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes or Over the Counter Use No